

**NOTICE OF PROPOSED REGULATION ADOPTION**

**California Code of Regulations  
Title 17. – Public Health  
Division 4 - California Institute For Regenerative Medicine  
Chapter 8**

**Date: January 22, 2010**

**Deadline for Submission of Written Comment: March 8, 2010 – 5:00 p.m.**

**Hearing Date: None scheduled.**

**Subject Matter of Proposed Regulations: Grant Administration Policy for Loan Recipients**

**Sections Affected:**

The proposed regulation adopts section 100801 of Title 17 of the California Code of Regulations.

**Authority:** Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

**Reference:** Section 125290.30, Health and Safety Code.

**Informative Digest/Policy Statement Overview:**

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in early 2005 with the passage of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The Act charges the ICOC with developing standards and criteria to make grant and loan awards and to develop standards and criteria for proper oversight of these grants and loans.

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

To achieve the goal of commercializing stem cell research-related products, CIRM will fund for-profit (commercial) research institutions in California via options that include grants and loans. As required by law, all CIRM-funded research activities must be conducted in the State of California. The goal of a loan program is to fund the translation of research into research tools, medical diagnostics and devices, and therapeutic products. These loans will be targeted at the funding gaps in product development that will serve to leverage participation by follow-on investors, such as venture capital and other capital markets, and result in more products that enter the market. For the State and CIRM, the advantage of a loan program versus a grant is the ability to recycle CIRM research funds, potentially enlarging the return for each CIRM research dollar expended. In addition to loan principal and interest, loans may also feature warrant coverage, depending on the type of loan, which will constitute additional interest-based return on the investment in light of risk posed.

In 2010, the California Institute for Regenerative Medicine (CIRM) will begin offering research loans to for-profit institutions. In 2009, the ICOC adopted a Loan Administration Policy to cover various administrative procedures that will apply to the review and administration of research loans and loan applications. That policy is the subject of a separate regulatory action. The Loan Task Force, a subcommittee of the ICOC, developed much of the policy.

Early in the task force's meetings in 2008, it was determined that virtually all of the Intellectual Property regulations that applied in the context of grants should also apply to loan recipients. The exception, of course, is the requirement of grantees to share profits and other revenues with the state. In the context of loans, revenue sharing is superfluous in light of the loan repayment and warrant provisions of the loan program.

Currently, the agency's IP regulations only apply to grants. A new regulation is necessary to extend certain provisions to loan recipients. To that end, and to ensure potential loan recipients in the Disease Team RFA are subject to the agency's IP regulations, CIRM proposes to adopt Section 100801 – Intellectual Property Provisions Applicable to Loan Recipients.

Proposed regulation 100801 incorporates the agency's consolidated IP regulations (sections 100600, *et seq.*), with the exception of regulation 100606, addressing revenue sharing. In addition, certain provisions of section 100602, that would require reporting of revenues, are exempted for the same reasons as the revenue sharing requirement. Subdivision (b) of the interim regulation is intended to ensure that a loan recipient cooperates with CIRM in identifying third parties that may be interested in acquiring the loan recipient's intellectual property in the event the loan recipient is otherwise planning to abandon the intellectual property.

### **Technical, Theoretical or Empirical Studies, Reports or Documents:**

#### **A. Documents or Laws:**

- Title 2, California Code of Regulations, sections 100600, *et seq.* – Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees (<http://www.cirm.ca.gov/cirm-operations/Regulations>)

#### **B. Public Input:**

Discussion and public input received at the following public meetings conducted by the Loan Task Force on 12/11/07, 1/16/08, 2/19/08, 3/11/08, 5/6/08; by the Finance Subcommittee on 9/20/08, 11/19/08; and ICOC on 8/13/08, 9/25/08, 1/30/09.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section “B” are available on CIRM's website, [www.cirm.ca.gov](http://www.cirm.ca.gov) under the “Meetings Transcripts” and “Meetings Minutes” links.

#### **Submittal of Comments:**

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on March 8, 2010. Comments regarding this proposed action may also be transmitted via e-mail to [loanipreg@cirm.ca.gov](mailto:loanipreg@cirm.ca.gov) or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than February 22, 2010.

**Effect on Small Business:**

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulation implements conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11342.610.

**Impact on Local Agencies or School Districts:**

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

**Costs or Savings to State Agencies:**

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

**Effect on Federal Funding to the State:**

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory action.

**Effect on Housing Costs:**

CIRM has made an initial determination that the proposed action will have no effect on housing costs.

**Significant Statewide Adverse Economic Impact Directly Affecting Businesses:**

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

**Cost Impacts on Representative Private Persons or Businesses:**

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

**Impact on the Creation, Elimination, or Expansion of Jobs:**

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

**Consideration of Alternatives:**

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

**Availability of Statement of Reasons and Text of Proposed Regulations:**

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

**Availability of Changed or Modified Text:**

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

**Agency Contact:**

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Counsel to the Chair

ICOC  
California Institute for Regenerative Medicine  
210 King Street  
San Francisco, CA 94107  
(415) 396-9100

or,

Nancy Koch  
California Institute for Regenerative Medicine  
(415) 396-9253

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, [www.cirm.ca.gov](http://www.cirm.ca.gov).

**Availability of Final Statement of Reasons:**

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at [www.cirm.ca.gov](http://www.cirm.ca.gov).